

## § 870.4400

to flow through the cardiopulmonary bypass circuit.

(b) *Classification*. Class II (performance standards).

### § 870.4400 Cardiopulmonary bypass blood reservoir.

(a) *Identification*. A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation.

(b) *Classification*. Class II (performance standards), except that a reservoir that contains a defoamer or filter is classified into the same class as the defoamer or filter.

### § 870.4410 Cardiopulmonary bypass in-line blood gas sensor.

(a) *Identification*. A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

(b) *Classification*. Class II (performance standards).

### § 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

(a) *Identification*. A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

(b) *Classification*. Class II (performance standards).

### § 870.4430 Cardiopulmonary bypass intracardiac suction control.

(a) *Identification*. A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

(b) *Classification*. Class II (performance standards).

### § 870.4450 Vascular clamp.

(a) *Identification*. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

(b) *Classification*. Class II (performance standards).

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### § 870.4475 Surgical vessel dilator.

(a) *Identification*. A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

(b) *Classification*. Class II (performance standards).

### § 870.4500 Cardiovascular surgical instruments.

(a) *Identification*. Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

[45 FR 7907–7971, Feb. 5, 1980, as amended at 54 FR 25049, June 12, 1989; 66 FR 38797, July 25, 2001]

### § 870.4875 Intraluminal artery stripper.

(a) *Identification*. An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arteriosclerotic arteries.)

(b) *Classification*. Class II (performance standards).

### § 870.4885 External vein stripper.

(a) *Identification*. An external vein stripper is an extravascular device used to remove a section of a vein.

(b) *Classification*. Class II (performance standards).

## Subpart F—Cardiovascular Therapeutic Devices

### § 870.5050 Patient care suction apparatus.

(a) *Identification*. A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

(b) *Classification*. Class II (performance standards).

### § 870.5150 Embolectomy catheter.

(a) *Identification*. An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli,